

Billing Code: 4163-18-P

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Evidence-Based Laboratory Medicine: Quality/Performance Measure Evaluation

Announcement Type: New

Funding Opportunity Number: CDC-CI07-710

Catalog of Federal Domestic Assistance Number: 93.064

Key Dates:

Letter of Intent Deadline: June 18, 2007

Application Deadline: July 17, 2007

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act [42 USC 247b(k)(2)], as amended.

Background: “The only way to know whether the quality of care is improving is to measure performance” according to the Institute of Medicine (*Performance Measurement: Accelerating Improvement*, 2006). Among the benefits from improving performance measurement, the IOM includes the following:

- improves the ability to provide better health care services
- catalyzes action to provide high-quality, patient-centered care consistently and efficiently
- reduces provider frustration and burdens from multiple conflicting requests for reports
- becomes a resource for internal quality improvement
- facilitates better access to information that is understandable, meaningful and important to patients, families and communities

Currently there is a paucity of evidence-based standards, guidelines and measures for evaluating laboratory medicine quality and performance in the pre- and post-analytic stages of the total testing process consistent with national health care and patient safety priorities for evaluating whether the provision and use of laboratory services is safe, timely, efficient, effective, equitable and patient-centered.

Purpose: The purpose of the program is to evaluate clinical laboratory practice by identifying evidence-based laboratory medicine quality/performance measures associated with the pre- and post-analytic stages of the total testing process, and to identify and address gaps and opportunities for improvement consistent with national health care priorities to improve public health. The primary objectives are to:

1. Provide an evidence base which systematically identifies and defines important gaps in laboratory medicine quality related to individuals or populations and/or patient safety health outcomes with demonstrated impacts (i.e., clinical and/or economic).
2. Identify, develop, and define laboratory medicine performance/quality measures that can be broadly implemented to evaluate performance associated with patient outcomes.
3. Identify interventions effective in improving performance.

This program addresses the “Healthy People 2010” focus area(s) of (1) Access to Quality Health Services. Potentially, one or more of the following “Healthy People 2010” focus areas may also be addressed as there are laboratory services related to these specific conditions for which both general and specific laboratory medicine service-related performance measures may be developed: (3) Cancer, (4) Chronic Kidney Disease, (5) Diabetes, (12) Heart Disease and Stroke, (13) HIV, (14) Immunizations and Infectious Diseases, (16) Maternal,

Infant, and Child Health, (19) Nutrition and Overweight, (24) Respiratory Diseases, and (25) Sexually Transmitted Diseases.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the Centers for Disease Control and Prevention: Healthy Healthcare Places: Increase the number of healthcare settings that provide safe, effective, and satisfying patient care. This relates to DHHS GPRA Goal #4: Improve the Quality of Health Care and Human Services and particularly Goal #4.1: *Promote the Appropriate Use of Effective Health Services.*

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address:

<http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm>.

Activities:

Awardee activities for this program are as follows:

- Provide leadership in identifying and defining evidence-based deficiencies and variation in laboratory medicine quality in the pre- and post-analytic phases of the total testing process related to national health care and patient safety priorities.
- Systematically review literature and available evidence concerning specific laboratory medicine quality problems and practices associated with variation in quality in the pre- and post- analytic phases of the total testing process, and identify performance and information gaps, and opportunities for improvement related to public health.
- Design new studies to identify and define laboratory medicine quality gaps and performance measures involving the collection and analysis of data appropriate for producing results to evaluate performance, including clinical and economic outcomes, and effectiveness of various practices.
- Identify, recruit, and collaborate with potential study contributors, subject matter experts, and expert reviewers.
- Analyze the data and information collected, and prepare written summaries.
- Select and conduct pilot studies.
- Evaluate clinical and economic outcomes associated with identified quality gaps, key variables, relevant practices and performance measures.

- Develop and define laboratory medicine quality/performance measures for evaluating and monitoring performance addressing identified evidence-based quality gaps consistent with improving the public's health (i.e., important health conditions and/or populations).
- Identify and recommend specific interventions (e.g., practices, processes, technologies, standards, guidelines) for which there is evidence or a demonstrable likelihood that they are effective at improving performance/quality with respect to the problem identified and the associated performance measure.
- Prepare manuscripts for peer-reviewed publications.

The above activities may be structured in three phases over three years for an individual performance measure as follows: (1) initial investigation and study design addressing performance measure topic area; (2) data collection and analysis; and (3) performance measure pilot testing, drafting reports and manuscripts

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC activities for this program are as follows:

- Provide awardee(s) information, including recent and ongoing results and findings from CDC-sponsored initiatives related to laboratory medicine quality, and other relevant background information including standards and practices.
- Assist awardee(s) in reviewing and obtaining relevant literature and available evidence.
- Assist awardee(s) by providing expertise and input in identifying laboratory medicine quality problems, informational gaps, potential performance measures, challenges and relevant issues.
- Assist awardee in identifying and recruiting potential study contributors, subject matter experts, and expert reviewers, and promote collaboration.
- Provide technical assistance in study design and data collection instrument development.
- Provide access to a health economist to assist with economic evaluations.
- Collaborate in analyzing the data and information collected, and in preparing written summaries and publications.
- Assist in the preparation of manuscripts for peer-reviewed publications.

II. Award Information

Type of Award: Cooperative Agreement

CDC's involvement in this program is listed in the Activities Section above.

Award Mechanism: U47

Fiscal Year Funds: 2007

Approximate Current Fiscal Year Funding: \$750,000

Approximate Total Project Period Funding: \$2,250,000 (This amount is an estimate, and is subject to availability of funds. Amount includes both direct and indirect costs.)

Approximate Number of Awards: 3

Approximate Average Award: \$250,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Individual Award Range: \$100,000

Ceiling of Individual Award Range: \$500,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August 31, 2007

Budget Period Length: 12 Months

Project Period Length: 3 years

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

III. Eligibility Information

III.1. Eligible Applicants

Eligible applicants that can apply for this funding opportunity are listed below:

- Public nonprofit organizations
- Private nonprofit organizations
- Small, minority, women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian tribes
- Indian tribal organizations

- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a letter from the state or local government as documentation of the status is required. Place this documentation behind the first page of the application form.

III.2. Cost Sharing or Matching

Cost sharing or matching funds are not required for this program.

III.3. Other

If a funding amount greater than the ceiling of the award range is requested, the application will be considered non-responsive and will not be entered into the review process. The applicant will be notified that the application did not meet the submission requirements.

Special Requirements:

If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified the application did not meet submission requirements.

- Late applications will be considered non-responsive. See section “IV.3. Submission Dates and Times” for more information on deadlines.
- Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting a grant, loan, or an award.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity use application form PHS 5161-1.

Electronic Submission:

CDC strongly encourages the applicant to submit the application electronically by utilizing the forms and instructions posted for this announcement on

www.Grants.gov, the official Federal agency wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms.

Registering your organization through www.Grants.gov is the first step in submitting applications online. Registration information is located in the “Get Started” screen of www.Grants.gov. While application submission through www.Grants.gov is optional, we strongly encourage you to use this online tool.

Please visit www.Grants.gov at least 30 days prior to filing your application to familiarize yourself with the registration and submission processes. Under “Get Started,” the one-time registration process will take three to five days to complete. We suggest submitting electronic applications prior to the closing date so if difficulties are encountered, you can submit a hard copy of the application prior to the deadline.

Paper Submission:

Application forms and instructions are available on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/forms.htm>.

If access to the Internet is not available, or if there is difficulty accessing the forms on-line, contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at 770-488-2700 and the application forms can be mailed.

IV.2. Content and Form of Submission

Letter of Intent (LOI):

Your LOI must be written in the following format:

- Maximum number of pages: 5
- Font size: 12-point unreduced, Times New Roman
- Double spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

The LOI must contain the following information:

- Goals and objectives

- Methods and technical approach
- Project management and staffing
- Budget – total funds requested

Application:

A Project Abstract must be submitted with the application forms. The abstract must be submitted in the following format:

- Maximum of one page.
- Font size: 12 point unreduced, Times New Roman
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch

The Project Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a technically literate lay reader. This Abstract must not include any proprietary/confidential information.

A project narrative must be submitted with the application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25 (If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.)
- Font size: 12 point unreduced, Times New Roman
- Double spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Number all pages of the application sequentially from page 1 (Application Face Page) to the end of the application, including charts, figures, tables, and appendices.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

The narrative should address activities to be conducted over the entire project period and must include the following items in the order listed:

- Purpose and need
- Goals and objectives
- Methods and technical approach
- Project management and staffing
- Measures of effectiveness to demonstrate accomplishment of program activities

- Timeline
- Evaluation plan
- Required resources with budget and justification
- Performance measures

Note: The budget and performance measures sections will not count toward page limitation.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitaes, Resumes, and Organizational Charts
- Letters of support
- References

No more than 5 electronic attachments should be uploaded per application.

The agency or organization is required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative

agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711.

Additional requirements that may request submittal of additional documentation with the application are listed in section “VI.2. Administrative and National Policy Requirements.”

IV.3. Submission Dates and Times

Letter of Intent (LOI) Deadline Date: June 18, 2007

CDC requests that an applicant submit an LOI if the applicant intends to submit a full application for this funding opportunity. Although the LOI is not required, not binding, and does not enter into the review of the subsequent application, it will be used to gauge the level of interest in this program and to allow CDC to plan the application review.

Application Deadline Date: July 17, 2007

Explanation of Deadlines: Applications must be received in the CDC

Procurement and Grants Office by 4:00 p.m. Eastern Time on the deadline date.

Applications may be submitted electronically at www.Grants.gov. Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the

application to www.Grants.gov. Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If submittal of the application is done electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an e-mail notice of receipt when HHS/CDC receives the application.

If submittal of the application is by the United States Postal Service or commercial delivery service, the applicant must ensure that the carrier will be able to guarantee delivery by the closing date and time. The applicant will be given the opportunity to submit documentation of the carrier's guarantee, if HHS/CDC receives the submission after the closing date due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time; or (2) significant weather delays or natural disasters. If the documentation verifies a carrier problem, HHS/CDC will consider the submission as having been received by the deadline.

If a hard copy application is submitted, HHS/CDC will not notify the applicant upon receipt of the submission. If questions arise on the receipt of the application, the applicant should first contact the carrier. If the applicant still has

questions, contact the PGO-TIM staff at (770) 488-2700. The applicant should wait two to three days after the submission deadline before calling. This will allow time for submissions to be processed and logged.

This announcement is the definitive guide on LOI and application content, submission address, and deadline. It supersedes information provided in the application instructions. If the application submission does not meet the deadline above, it will not be eligible for review, and will be discarded by HHS/CDC. The applicant will be notified the application did not meet the submission requirements.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care.

- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- Awardees may not generally use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. Any such proposed spending must be identified in the budget.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.

If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

The recommended guidance for completing a detailed justified budget can be found on the CDC Web site, at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

LOI Submission Address: Submit the LOI by express mail, delivery service, fax,
or E-mail to:

Susan R. Snyder

CDC / NCPDCID

1600 Clifton Road, Mailstop G-23

Atlanta, GA 30333

Telephone: 404-718-1001

Fax: 404-718-1080

E-mail: ssnyder@cdc.gov

Application Submission Address:

Electronic Submission:

HHS/CDC strongly encourages applicants to submit applications electronically at www.Grants.gov. The application package can be downloaded from www.Grants.gov. Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. E-mail submissions will not be accepted. If the applicant has technical difficulties in Grants.gov, customer service can be reached by E-mail at <http://www.grants.gov/CustomerSupport> or by phone at 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7:00 a.m. to 9:00 p.m. Eastern Time, Monday through Friday.

HHS/CDC recommends that submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: “BACK-UP FOR ELECTRONIC SUBMISSION.” The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

The applicant must submit all application attachments using a PDF file format when submitting via Grants.gov. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than PDF may result in the file being unreadable by staff.

OR

Paper Submission:

Applicants should submit the original and two hard copies of the application by mail or express delivery service to:

Technical Information Management – CDC-CI07-710

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road

Atlanta, GA 30341

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the “Purpose” section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. The measures of effectiveness must be submitted with the application and will be an element of evaluation.

The application will be evaluated against the following criteria:

1. Methods and Technical Approach (30 points)

- Does the applicant clearly and succinctly describe the steps to be taken in the planning and implementation of the proposed cooperative agreement?
- Are the methods to be used to carry out the responsibilities of the proposed cooperative agreement feasible and explained in sufficient detail?

2. Project Management and Staffing (30 points)

- Does the applicant describe a project management and staffing plan, and demonstrate sufficient knowledge, expertise, and other resources required to perform the responsibilities in this project?
- Does the applicant describe the staff qualifications and the time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project?

3. Goals and Objectives (20 points)

- Does the applicant clearly describe an understanding of the objectives of this project, the relevance of the proposal to the stated objectives, and any unique characteristics of the organizations and populations studied?
- Are the goals and objectives for the proposal measurable, specific, and achievable?

4. Evaluation Plan and Timeline (20 points)

- Does the applicant describe the schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments?

5. Proposed Budget (reviewed but not scored)

- Is the proposed budget reasonable, clearly justified, and consistent with the intended use of funds?

6. Performance Goals (reviewed but not scored)

- Does the applicant describe what is expected to be achieved in sufficient detail, and how the proposed activities will produce evidence for a positive public health impact?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness jointly by NCPDCID and PGO.

Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified the application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the “V.1. Criteria” section above. The objective review panel will consist of CDC employees from outside the funding division who will evaluate the technical merit of the application for the purpose of advising the awarding official. As part of the review process, the application will:

- Receive a written Summary Statement of the findings of the Objective Review Panel.
- Receive a vote of approval or disapproval and an approval score.
- Receive a second programmatic level review by Division senior staff.

Applications will be funded in order by score and rank determined by the review panel.

CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Announcement Award Dates

August 31, 2007

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer and emailed to the program director and a hard copy mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 and Part 92, as appropriate. The following additional requirements apply to this project:

- AR-10 Smoke-Free Workplace Requirements

- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-21 Small, Minority, and Women-Owned Business
- AR-23 States and Faith-Based Organizations
- AR-25 Release and Sharing of Data

Additional information on the requirements can be found on the CDC Web site at the following Internet address:

http://www.cdc.gov/od/pgo/funding/Addtl_Reqmnts.htm.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

VI.3. Reporting Requirements

The applicant must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as the non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.
 - c. New Budget Period Program Proposed Activity Objectives.
 - d. Budget.
 - e. Measures of Effectiveness.
 - f. Additional Requested Information.
2. Annual progress report, due 90 days after the end of the budget period.
3. Financial status report and annual progress report, no more than 90 days after the end of the budget period.
4. Final performance and Financial Status reports, no more than 90 days after the end of the project period.

The reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

CDC encourages inquiries concerning this announcement.

For general questions, contact:

Technical Information Management Section

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road

Atlanta, GA 30341

Telephone: 770-488-2700

For program technical assistance, contact:

Susan R. Snyder, Project Officer

Department of Health and Human Services

CDC/CCID/NCPDCID/DLS

1600 Clifton Road – Mailstop G-23

Atlanta, GA 30329-4018

Telephone: 404-718-1001

Fax: 404-718-1080

E-mail: ssnyder@cdc.gov

For financial, grants management, or budget assistance, contact:

Yolanda Sledge, Grants Management Specialist

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, Mail stop: E-14

Atlanta, GA 30341

Telephone: (770) 488-2787

E-mail: yiso@cdc.gov

CDC Telecommunications for the hearing impaired or disabled is available at:

TTY 770-488-2783.

VIII. Other Information

Other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: <http://www.cdc.gov/od/pgo/funding/FOAs.htm>.

CDC Home Page: <http://www.cdc.gov>

CDC Funding Web Page: <http://www.cdc.gov/od/pgo/funding/funding.htm>

CDC Forms Web Page: <http://www.cdc.gov/od/pgo/forminfo.htm>
